SOP 003: SOP for Taking Minutes and Communicating Decisions to Investigators

1. Purpose
To describe and document the procedure for recording FOMREC meeting minutes and communicating FOMREC decisions to investigators.

2. Scope
Recording of minutes and communicating decisions to investigators.

3. Responsible Persons
FOMREC administrative staff, FOMREC members assigned to review protocols and investigators.

4. Background
Both national and international regulations require FOMREC to maintain adequate documentation of its activities. These minutes along with any other documents must provide sufficient detail about the deliberation, decisions and actions of FOMREC and its members.

Minutes will be taken at all FOMREC meetings including emergency meetings. Both soft and hard copies of the minutes and other FOMREC documents will be securely kept for a minimum of 10 years and then archived.

5. Procedures
- The minutes of FOMREC meetings will include but not be limited to the following:
  I. Attendance of research and ethics committee members, co-opted members, FOMREC administrative staff, investigators and other researchers present
  II. Separate deliberations, actions and decisions made on each of the applications being reviewed including amendments and protocol deviations
  III. Report from expedited reviewer and discussion
  IV. Circumstances in which members with conflict of interest did not participate in deliberation and voting
  V. Any other discussions and decisions taken by FOMREC

- The FOMREC administrative staff will prepare the minutes of the meeting and copies of which will be provided to FOMREC members in a period of 1 week.
- Investigators whose protocols were reviewed will receive communication in writing, within two (2) weeks, about FOMREC decisions detailing why the decision was made.
i. In case the decision made was passed with minor changes, the reviewer of the corrections will be indicated. The investigator(s) will submit the corrected version of the protocol directly to the research administration office which will relay it to the designated reviewer.

ii. In case major changes are required, the investigator shall be advised to resubmit the corrected version of the proposal/protocol.

iii. In case of a rejection, the investigator shall be given a summary of the reasons for the rejection.

6. Minutes will be kept on file at the research administration office.
7. Approved proposals and consent forms shall be stamped and archived.
8. Approval letters shall contain protocol version and protocol number.